REMARKS

This application is a national phase filing under 35 U.S.C. §371 of International Application No. PCT/JP2004/019226 filed May 30, 2007. The PCT application, with an International Filing date of December 22, 2004, claims priority to Japanese Patent Application Serial No. 2003-425706, filed December 22, 2003. At the time the application was filed, claims 1-6 were pending and claims 1, 4 and 5 were amended in a Preliminary Amendment filed with the application. Claim 1 and Claims 6-9 are amended above. Claims 1, 3 and 5-10 are currently pending in the application.

Rejections Under 35 U.S.C. §112

The Office Action stated that claims 1, 3, 5 and 7-10 were rejected as indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. Specifically, claims 1 and 9 were objected to for reciting "promyelotic" rather than "promyelocytic". In response, applicant has amended claims 1 and 9 to correct this issue and applicant has also amended claim 6, because a review of the claims uncovered "promyleotic" in this claim as well.

Additionally, claims 1 and 7 were rejected as confusing due to inconsistent wording, including the use of "analyzing the degree of thrombophilia" in the preamble and "indicative of an increased risk of thrombophilia" as the final element of the claim. Applicant has amended claim 1 to make the claim more clear and less confusing.

Claims 1 and 9 were also rejected as ambiguous in reciting "patients suffering from one or more of the following "conditions" acute or chronic myeloid leukemia, acute promyelocytic leukemia, pulmonary embolism, cerebral infarction, veno-occlusive disease, acute lymphocytic leukemia, and deep vein thrombosis". The Office Action states that it is unclear how the diseases listed are structurally and functionally related to vWF-cp and either of "degree of thrombophilia" or "increased risk of thrombophilia". With regard to pulmonary embolism and cerebral infarction, one of skill in the art would know that thrombosis may be a precursor to the development of either condition, and one of skill would also know that vWFcp is a key mediator of thrombosis and thus that vWFcp may be implicated in these conditions. With regard to veno-

occlusive disease and deep vein thrombosis, thrombosis is known by those of skill in the art to either be a causative agent or a symptom or consequence of each of these disease states. For the same reasons discussed above, one of skill in the art would then appreciate the correlation between vWFcp and these conditions. With regard to acute or chronic myeloid leukemia, acute promyelocytic leukemia, acute lymphocytic leukemia, claims 1, 6 and 9 have been amended to remove these indications.

The Office Action also rejected claims 7-10 for not meeting the statutory enablement requirement. Specifically, the Office Action stated that the invention has not been enabled for body fluids such as "lymph, a thymic fluid, ascites fluid, an amniotic fluid, gastric juices, urine, pancreatic juices, spinal fluid, and saliva", though the Office Action stated that the invention is enabled for blood plasma. Without admitting to the propriety of the rejection of these additional fluids as not enabled, and in the interests of expedited prosecution, applicant has amended claims 7-10 to be more limited in scope. Specifically, applicant has limited claim 7 (and thus claims 8-10 as well) to blood plasma, whole blood, and serum. As discussed above, the Office Action stated that the invention was enabled for blood plasma. As such, the addition of whole blood and serum to the claim is also enabled since a person of skill in the art would recognize that detection of a blood-borne factor that has been shown to exist in blood plasma can also be accomplished in whole blood or serum because each have blood plasma as a portion of their composition.

The Office Action also states that claim 8 recites improper Markush language. Claim 8 has been amended such that this is no longer an issue.

Rejections under 35 USC §102

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *See Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984).

The Office Action states that claims 1 and 5-9 are rejected as anticipated by Scheiflinger et al. (US 2004/0214346 A1). The Office Action states that Scheiflinger et al. teaches "combining a blood sample from the patient with anti-vWFcp antibody that specifically binds to vWFcp immobilized into a

solid phase and then detecting binding and complex formation of the anti-vWFcp antibody to vWFcp antigen using the immunological assay kit and method". Respectfully, applicant asserts that Scheiflinger et al. requires that the anti-vWFcp antibody must be generated by the patient and thus present in the blood sample analyzed and that it is the anti-vWFcp antibody generated by the patient that is detected, and not vWFcp itself. Specifically, please refer to the abstract of Scheiflinger et al, where in it states "[t]his invention relates to a kit to be used in an assay system for determination of an anti-von Willebrand Factor-cleaving protease *antibody* in a sample" and "[t]he kit can be used in a method for determination of anti-vWFcp *antibodies* from a patient, for the diagnosis of disorders associated with the occurrence of anti-vWFcp antibodies…". Crucially, the present invention detects vWFcp itself, and not an antibody to vWFcp. Thus, the Scheiflinger reference requires the existence of an anti-vWFcp antibody, something that is not present in the current invention. Additionally, Scheiflinger et al. teaches that an anti-vWFcp antibody may be used as an indicator for TTP, but that vWFcp itself cannot be used in the diagnosis for TTP. *See* Scheiflinger et al., figures 1 and 3. Applicant asserts that the present invention uses vWFcp itself in the diagnosis of disease.

The Office Action further states that claims 1 and 7-9 are rejected as inherently anticipated by Konetschny et al. (Development of a Highly Sensitive and Specific Enzyme-linked Immunosorbent Assay for the Detection of ADAMTS-13 in Human Plasma, Blood 102(11) Abstract #4062 (November 16, 2003)) in light of Scheiflinger et al.

The Federal Circuit has said"[i]nherency…may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2s 1746, 1749 (Fed. Cir. 1991). With regard to the current rejection, the Office Action states Scheiflinger et al. teaches that "thrombosis as taught in the method of Konetschny et al. is manifested in patients suffering from cancer-associated TM in [0034]." Without admitting to the propriety of the rejection, Applicant has amended claims 1, 6 and 9 such that cancer-associated TM indications have been removed. As such, Applicant believes this rejection is now moot.

CONCLUSION

It is believed that the application is in condition for allowance, and such action is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, the Examiner is invited to telephone the undersigned attorney at the telephone number provided.

Respectfully submitted,

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